General

Guideline Title

Emergency contraception.

Bibliographic Source(s)

Clinical Effectiveness Unit. Emergency contraception. London (UK): Faculty of Sexual and Reproductive Healthcare (FSRH); 2012 Jan. 21 p. [71 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Faculty of Sexual and Reproductive Healthcare (FSRH). Emergency contraception. London (UK): Faculty of Sexual and Reproductive Healthcare (FSRH); 2011 Aug. 21 p. [71 references]

Recommendations

Major Recommendations

The recommendation grades (A to C, Good Practice Point) are defined at the end of the "Major Recommendations" field.

Details of Changes to Original Guidance Document: The original version of this Clinical Effectiveness Unit (CEU) Guidance Document (issued in August 2011) contained some inconsistencies that the CEU has corrected in this version. These amendments are as follows: additional recommendation regarding offering a copper-beating intrauterine device (Cu-IUD) to eligible women presenting between 0 and 120 hours of unprotected sexual intercourse (UPSI) or within 5 days of expected ovulation added (pages ii and 8 of the guideline document); references 12 and 13 updated (page 11 of the guideline document); and acknowledgement of chart designer added to Appendix 2 (page 15 of the guideline document).

What Methods Should Be Offered to Women Requesting Emergency Contraception?

- Health professionals should discuss individual need for emergency contraception (EC) and inform women about the different methods with regard to efficacy, adverse effects, interactions, medical eligibility and need for additional contraceptive precautions. (Good Practice Point)
- The copper-bearing intrauterine device (Cu-IUD) can be inserted up to 120 hours after the first episode of unprotected sexual intercourse (UPSI) or within 5 days of the earliest expected date of ovulation. (Grade C)
- All eligible women presenting between 0 and 120 hours of UPSI or within 5 days of expected ovulation should be offered a Cu-IUD because of the low documented failure rate. (Grade B)
- The efficacy of ulipristal acetate (UPA) has been demonstrated up to 120 hours and can be offered to all eligible women requesting EC during this time period. It is the only oral EC licensed for use between 72 and 120 hours. (Grade A)

- The efficacy of levonorgestrel (LNG) has been demonstrated up to 96 hours; between 96 and 120 hours efficacy is unknown. Use of LNG beyond 72 hours is outside the product licence. (Grade A)
- If a service or health professional is unable to provide a method of EC, local referral mechanisms should facilitate timely access to a service that can provide the woman's preferred method. (Good Practice Point)
- Ideally an emergency intrauterine device (IUD) should be inserted at first presentation, but where this is not possible oral EC can be given in the interim, and the woman advised to return at the earliest appropriate time. (Good Practice Point)

Future/Ongoing Contraception

- Women should be advised that oral EC methods do not provide contraceptive cover for subsequent UPSI and that they will need to use contraception or refrain from sex to avoid further risk of pregnancy. (Grade B)
- If a woman is likely to continue to be at risk of pregnancy or has expressed a preference to start contraception immediately after EC, a health professional may "quick start" combined hormonal contraception (excluding co-cyprindiol), the progestogen-only pill (POP) or implant, providing the woman has been appropriately informed and advised to have a pregnancy test in ≥3 weeks. (Good Practice Point)
- Women requesting the progestogen-only injectable after EC should ideally be offered an alternative method until pregnancy can be excluded. The injectable should be started immediately only if other methods are not appropriate or acceptable and the woman has been appropriately informed and advised to have a pregnancy test in ≥3 weeks. (Good Practice Point)
- Following administration of LNG, women continuing to use a hormonal method of contraception should be advised to use additional contraceptive precautions for 7 days (2 days for POP, 9 days for Qlaira®). (Grade C)
- Following administration of UPA, women continuing to use a hormonal method of contraception should be advised to use additional contraceptive precautions for 14 days (9 days for POP, 16 days for Qlaira). (Good Practice Point)

Drug Interactions

- Women taking liver enzyme-inducing drugs (or who have stopped taking this medication within the last 28 days) should be advised that a Cu-IUD is the only method of EC not affected by these drugs. (Grade A)
- Women taking liver enzyme-inducing drugs, including post-exposure human immunodeficiency virus (HIV) prophylaxis after sexual exposure (or who have stopped within the last 28 days), and who decline or are not eligible for a Cu-IUD, should be advised to take a dose of 3 mg LNG (two Levonelle® tablets) as soon as possible within 120 hours of UPSI (outside the product licence). The efficacy of LNG after 96 hours is uncertain. (Grade C)
- Women taking liver enzyme-inducing drugs should be advised not to use UPA during or within 28 days of stopping taking this medication. (Grade C)
- Women should be advised not to use UPA if they are currently taking drugs that increase gastric pH (e.g., antacids, histamine H_2 antagonists, and proton pump inhibitors). (Grade C)

Side Effects

- Women should be advised to seek medical advice if they vomit within 2 hours of taking LNG or 3 hours of UPA administration. A repeat dose of the same method or a Cu-IUD may be offered if appropriate. (Good Practice Point)
- Women should be advised about menstrual disturbances after oral EC use. If there is any doubt about whether menstruation has occurred, a pregnancy test should be performed ≥3 weeks after UPSI has occurred. (Good Practice Point)

Multiple Use in the Same Cycle

- LNG can be used more than once in a cycle or for a recent indication even if there has been an earlier episode of UPSI outside the treatment window (>120 hours). (Grade C)
- The Clinical Effectiveness Unit (CEU) does not currently support use of UPA more than once per cycle or if there has been another episode of UPSI outside the treatment window (>120 hours). (Good Practice Point)

Clinical Examinations and Investigations

- Women attending for EC should be offered the opportunity to undergo testing for sexually transmitted infections (STIs) including HIV. (Grade C)
- For women at risk of STIs, if test results are unavailable before IUD insertion, health professionals should consider prophylactic antibiotics at least to cover *Chlamydia trachomatis*. (Good Practice Point)

Advance Provision

- Health professionals should inform women about availability of EC and when it can be used. Advance supply may be considered but there is no evidence to support routine provision. (Good Practice Point)

Definitions:

Grading of Recommendations

A: Evidence based on randomised controlled trials (RCTs)

B: Evidence based on other robust experimental or observational studies

C: Evidence is limited but the advice relies on expert opinion and has the endorsement of respected authorities.

Good Practice Point: Where no evidence exists but where best practice is based on the clinical experience of the multidisciplinary group.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

- Unprotected sexual intercourse
- Potential contraceptive failure
- Unintended pregnancy
- Sexually transmitted infection

Guideline Category

Counseling

Evaluation

Management

Prevention

Risk Assessment

Clinical Specialty

Emergency Medicine

Family Practice

Internal Medicine

Obstetrics and Gynecology

Preventive Medicine

Intended Users

Advanced Practice Nurses

Health Care Providers

Nurses

Pharmacists

Physician Assistants

Physicians

Public Health Departments

Guideline Objective(s)

- To summarise the available evidence on emergency contraception (EC) and provide guidance to health professionals providing EC
- To update previous Faculty of Sexual and Reproductive Healthcare (FSRH) guidance

Target Population

Women seeking emergency contraception

Interventions and Practices Considered

1. Clinical examination and investigations
    - Offering testing for sexually transmitted infections (STIs)
    - Consideration of prophylactic antibiotics before intrauterine device (IUD) insertion
    - Counselling patients regarding emergency contraception, including advice on drug interactions and side effects
2. Emergency contraception including
    - Copper-bearing IUD (Cu-IUD)
    - Levonorgestrel (LNG)
    - Ulipristal acetate (UPA)
3. Follow-up
    - Pregnancy test
    - Local referral as indicated
    - STI screening
    - Cu-IUD removal
    - Provision of ongoing contraception

Major Outcomes Considered

- Failure rates of emergency contraception (EC) methods, unintended pregnancy rate
- Drug interactions and side effects
- Pelvic infection rate after intrauterine device insertion

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Evidence is identified using a systematic literature review and electronic searches are performed for: MEDLINE (CD Ovid version) (1996–2011); EMBASE (1996–2011); PubMed (1996–2011); The Cochrane Library (to 2011), and the US National Guideline Clearinghouse. The searches are performed using relevant medical subject headings (MeSH), terms and text words. The Cochrane Library is searched for relevant systematic reviews, meta-analyses, and controlled trials relevant to emergency contraception. Previously existing guidelines from the Faculty of Sexual and Reproductive Healthcare (FSRH) (formerly the Faculty of Family Planning and Reproductive Health Care), the Royal College of Obstetricians and Gynaecologists (RCOG), the World Health Organization (WHO), and the British Association for Sexual Health and HIV (BASHH), and reference lists of identified publications, are also searched. Similar search strategies have been used in the development of other national guidelines.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Not Given)

Rating Scheme for the Strength of the Evidence

Not stated

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Selected key publications are appraised using standard methodological checklists similar to those used by the National Institute for Health and Clinical Excellence (NICE). All papers are graded according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system. Recommendations are graded using a scheme similar to that adopted by the Royal College of Obstetricians and Gynaecologists (RCOG) and other guideline development organisations. The clinical recommendations within this guidance are based on evidence whenever possible. Summary evidence tables are available on request from the Clinical Effectiveness Unit (CEU).

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Clinical Effectiveness Unit (CEU) guidance is developed in collaboration with the Clinical Effectiveness Committee of the Faculty of Sexual and Reproductive Healthcare (FSRH). The CEU guidance development process employs standard methodology and makes use of systematic literature review and a multidisciplinary group of professionals. The multidisciplinary group is identified by the CEU for their expertise in the topic area and typically includes health professionals working in family planning, sexual and reproductive health care, general practice, other allied specialties, and user representation. In addition, the aim is to include representatives from the FSRH Clinical Effectiveness, Education and Clinical Standards Committees and FSRH Council in the multidisciplinary group.

The draft one guidance document is written providing recommendations and good practice points based on the literature review. The CEU has overall responsibility for writing the guidance document. The multidisciplinary group and other peer reviewers should highlight inconsistencies,

errors, omissions or lack of clarity. Peer review is conducted by a multidisciplinary group comprising stakeholders and including service user representation; representation from the FSRH Education Committee; and where possible representation from the FSRH Clinical Effectiveness Committee (CEC) and FSRH Council. At this stage the CEU convenes a one-day meeting of the multidisciplinary group. Preparation of draft two guidance document is based on written comments from the multidisciplinary group.

Rating Scheme for the Strength of the Recommendations

Grading of Recommendations

A: Evidence based on randomised controlled trials (RCTs)

B: Evidence based on other robust experimental or observational studies

C: Evidence is limited but the advice relies on expert opinion and has the endorsement of respected authorities

Good Practice Point: Where no evidence exists but where best practice is based on the clinical experience of the multidisciplinary group

Cost Analysis

The guideline developers reviewed published cost analyses.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Peer review of the draft two guidance document is performed by the multidisciplinary group, the Faculty of Sexual and Reproductive Healthcare (FSRH) Clinical Effectiveness Committee (CEC), and two independent peer reviewers. Preparation of the draft three guidance document is based on written comments from the peer reviewers. Peer review of draft three guidance document is conducted by the multidisciplinary group and FSRH CEC. Preparation of draft four guidance document is based on written comments from the peer reviewers. Peer review of draft four guidance document by the multidisciplinary group using a consensus process is completed. Preparation of the draft five guidance document is based on consensus scoring and comments of peer reviewers. The draft document is published on the Faculty Web site for 1 month for public consultation. The Clinical Effectiveness Unit (CEU)'s response to the consultation is approved by FSRH CEC. The final draft is prepared.

Proofreading of the guidance document is then performed by three members of the CEU team independently, and comments are collated and sent back by the Unit Director. The final guidance document is published by the FSRH. A portable document format (PDF) version of the guidance and the CEU's response to consultation comments are available on the FSRH website.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate use of emergency contraception
Prevention of unintended pregnancy

Potential Harms

Side Effects

- *Copper-Bearing Intrauterine Device (Cu-IUD)*: Pain is a common side effect associated with insertion.
- *Levonorgestrel (LNG)/Ulipristal Acetate (UPA)*: Headache, nausea and altered bleeding patterns are side effects common to oral emergency contraception (EC). Other reported side effects of UPA and LNG include headaches, abdominal pain, dysmenorrhoea and dizziness.

Drug Interactions

- *LNG*: Drugs that induce enzymes have the potential to decrease the contraceptive efficacy of LNG whilst using them and for 28 days afterwards. Women on liver enzyme-inducing drugs or who have stopped using them (≤28 days ago) who require EC should be offered a Cu-IUD as the efficacy is not affected by drugs. However, in women who are ineligible or who do not wish an intrauterine method a single 3 mg dose of LNG (two Levonelle® tablets) may be administered (outside product licence), although there is no empirical evidence to support this. In certain circumstances human immunodeficiency virus (HIV) post-exposure prophylaxis after sexual exposure (PEPSE) and EC may be required simultaneously. Although it can take several days for liver enzyme-inducing drugs to take effect, the exact mechanisms of LNG's action are unknown and there have been no interaction studies looking at the impact of dual administration of LNG and PEPSE. Therefore, the Clinical Effectiveness Unit (CEU) recommends 3 mg LNG (two tablets) if a Cu-IUD is not available or not acceptable.
- *UPA*: The Summary of Product Characteristics (SPC) states that it is not advisable to use UPA with liver enzyme-inducing drugs and the CEU therefore recommends that it is not used in women using liver enzyme-inducing drugs and for 28 days after these drugs are stopped. The SPC also states that UPA should not be used concomitantly with drugs that increase gastric pH. The CEU does not currently support doubling the dose of UPA when using drugs that may reduce UPA's efficacy. UPA itself may reduce the contraceptive efficacy of ongoing hormonal contraception. As a progesterone receptor modulator it blocks the action of progestogen and therefore in theory could reduce the efficacy of contraceptives containing progestogen.

Contraindications

Contraindications

Copper-Bearing Intrauterine Device (Cu-IUD)

Use of a Cu-IUD for emergency contraception (EC) carries the same contraindications as routine Cu-IUD insertion. Risk of sexually transmitted infections (STIs), previous ectopic pregnancy, age and nulliparity are not contraindications to use.

Ulipristal Acetate (UPA)

There are currently no recommendations on the use of UPA within UK Medical Eligibility Criteria for Contraceptive Use (UKMEC). Although there has been limited inclusion of under-18s in clinical trials of UPA, age is not listed as a contraindication within the Summary of Product Characteristics (SPC). UPA is licensed for use in under-18s and the CEU supports the use of all EC methods in young people.

The SPC states that contraindications to use include a hypersensitivity to UPA or any of the other components, and also pregnancy. Use is not recommended in women with severe asthma insufficiently controlled by oral glucocorticoids. In addition, the SPC advises caution in women with hepatic dysfunction, hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.

The SPC states that after intake of UPA, breastfeeding is not recommended for up to 36 hours.

Qualifying Statements

Qualifying Statements

The recommendations should be used to guide clinical practice but they are not intended to serve alone as a standard of medical care or to replace clinical judgement in the management of individual cases.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Audit Criteria/Indicators

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Timeliness

Identifying Information and Availability

Bibliographic Source(s)

Clinical Effectiveness Unit. Emergency contraception. London (UK): Faculty of Sexual and Reproductive Healthcare (FSRH); 2012 Jan. 21 p. [71 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2003 Jun (revised 2012 Jan)

Guideline Developer(s)

Faculty of Sexual and Reproductive Healthcare - Professional Association

Source(s) of Funding

Faculty of Sexual and Reproductive Healthcare

Guideline Committee

Clinical Effectiveness Committee

Composition of Group That Authored the Guideline

Guideline Development Group: Dr Louise Melvin, Director, Clinical Effectiveness Unit; Ms Julie Craik, Researcher, Clinical Effectiveness Unit; Dr Pauline McGough, Joint Clinical Director, Sandyford, Glasgow; Dr Najia Aziz, FSRH Education Committee representative, Specialty Trainee, Community Sexual & Reproductive Health, Ella Gordon Unit, St Mary's Hospital, Portsmouth; Dr Sharon Cameron, Consultant Gynaecologist, Family Planning and Well Woman Clinic, Chalmers Sexual Health Centre, Edinburgh; Dr Charlotte Cogswell, Associate Specialist, Department of Sexual and Reproductive Health, Llanyrafon House, Cwmbran, Gwent; Ms Caroline Donnelly, Practice Development Nurse, Sandyford, Glasgow; Dr Miranda Farmer, General Practitioner, Sex, Drugs and HIV Group of the Royal College of General Practitioners, Manchester Road Medical Centre, Knutsford, Cheshire; Dr Kate Guthrie, Consultant in Sexual and Reproductive Health, Conifer House, Hull; Mrs Lynn Hearton, FSRH Clinical Effectiveness Committee and user representative, Helpline and Information Services Manager, Family Planning Association, London; Dr Praveen Jayadeva, FSRH Clinical Standards Committee representative, Career Grade Trainee in Sexual and Reproductive Health, Lewisham Healthcare NHS Trust, London; Dr Noreen Khan, Consultant in Community Gynaecology Sexual and Reproductive Health, Palatine CASH Services, Manchester; Dr Paul O'Brien, Associate Specialist, Westside Contraceptive Services, St Charles Hospital, London; Miss Joanna Peacham, Community Pharmacist, Brocklehurst Chemists Ltd, Hull; Dr Rudiger Pittrof, Consultant in Community Sexual and Reproductive Health, Streatham Hill Health Centre, London; Dr Rashmi Ronghe, Subspecialty Trainee in Sexual and Reproductive Health, Sandyford, Glasgow; Professor James Trussell, Professor of Economics and Public Affairs, Princeton University and Visiting Professor, The Hull York Medical School, Hull; Dr Anne Webb, Consultant in Sexual and Reproductive Healthcare, Central Abacus, Liverpool

Administrative support to the Clinical Effectiveness Unit (CEU) team was provided by Ms Janice Paterson.

Financial Disclosures/Conflicts of Interest

Declared interests: Dr Sharon Cameron and Dr Anne Webb were principal investigators for an emergency contraception (EC) study funded by HRA Pharma.

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Faculty of Sexual and Reproductive Healthcare (FSRH). Emergency contraception. London (UK): Faculty of Sexual and Reproductive Healthcare (FSRH); 2011 Aug. 21 p. [71 references]

Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) from the Faculty of Sexual and Reproductive Healthcare Web site .

Print copies: Available from the Faculty of Sexual and Reproductive Healthcare, 27 Sussex Place, Regent's Park, London NW1 4RG

Availability of Companion Documents

Discussion points and questions for the emergency contraception guidance developed by the Faculty of Sexual and Reproductive Healthcare Education Committee are available in the original guideline document .

In addition, auditable outcomes are provided in the original guideline document .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI on July 5, 2005. This summary was updated by ECRI Institute on May 15, 2008. This NGC summary was updated by ECRI Institute on December 6, 2011. This NGC summary was updated by ECRI Institute on March 7, 2012.

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